



BILLING CODE: 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2016-0057]

J.R. Simplot Company; Availability of Preliminary Finding of No Significant Impact, Preliminary Plant Pest Risk Similarity Assessment, and Preliminary Determination for an Extension of a Determination of Nonregulated Status for X17 and Y9 Potato Varieties

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has reached a preliminary decision to extend our determination of nonregulated status of J.R. Simplot Company's (Simplot) Innate™ Potato designated as Russet Burbank event W8 (the antecedent potato event) to Simplot's Ranger Russet variety (X17) and Atlantic variety (Y9) potatoes. Simplot's X17 and Y9 potatoes have been genetically engineered for late blight resistance, low acrylamide potential, lowered reducing sugars, and reduced black spot using the same genetic constructs used to transform the antecedent potato event. We are making available for public comment our preliminary determination, preliminary plant pest risk similarity assessment, and preliminary finding of no significant impact for the proposed determination of nonregulated status.

DATES: We will consider all comments that we receive on or before [Insert date 30 days after date of publication in the Federal Register].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to
<http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0057>.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2016-0057, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

The J.R. Simplot Company extension request, our preliminary determination, preliminary plant pest risk similarity assessment, preliminary finding of no significant impact, and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0057> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

Supporting documents and any comments we received regarding our determination of nonregulated status of the antecedent organism (potato event W8) can be found at <http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0076>. Supporting documents may also be found on the APHIS Web site for X17 and Y9 (the organisms under evaluation) under APHIS Petition Number 16-064-01p, and the antecedent organism (potato event W8) under APHIS Petition Number 14-093-01p.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Biotechnology Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 851-3954, email: john.t.turner@aphis.usda.gov. To obtain

copies of the supporting documents, contact Ms. Cindy Eck at (301) 851-3885, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Under the authority of the plant pest provisions of the Plant Protection Act (PPA) (7 U.S.C. 7701 et seq.), the regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Further, the regulations in § 340.6(e)(2) provide that a person may request that APHIS extend a determination of nonregulated status to other organisms. Such a request must include information to establish the similarity of the antecedent organism and the regulated article in question.

In a notice¹ published in the Federal Register on September 2, 2015 (80 FR 53101-53102, Docket No. APHIS-2014-0076), APHIS announced our determination of nonregulated status of the J.R. Simplot Company's (Simplot) Innate™ Potato designated as Russet Burbank event W8, which has been genetically engineered for late blight resistance, low acrylamide potential,

¹ To view the notice, our determination, supporting documents, and the comments we have received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0076>.

reduced black spot bruising, and lowered reducing sugars. APHIS has received a request from Simplot for an extension of that determination of nonregulated status to its Ranger Russet variety (X17) and Atlantic variety (Y9) potatoes (APHIS Petition Number 16-064-01p). In the extension request, Simplot named the previously deregulated W8 potato event as the antecedent organism. Like the antecedent, X17 and Y9 are genetically engineered for late blight resistance, low acrylamide potential, reduced black spot bruising, and lowered reducing sugars. In its request, Simplot stated that X17 and Y9 potatoes were produced by using the same genetic construct that was used to transform the antecedent potato and, based on the similarity, is unlikely to pose a plant pest risk. Therefore, the request stated that X17 and Y9 potatoes should not be regulated articles under APHIS' regulations in 7 CFR part 340.

As part of our decisionmaking process regarding a genetically engineered organism's regulatory status, APHIS evaluates the plant pest risk of the regulated article. In section 403 of the PPA, "plant pest" is defined as any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant product: A protozoan, a nonhuman animal, a parasitic plant, a bacterium, a fungus, a virus or viroid, an infectious agent or other pathogen, or any article similar to or allied with any of the foregoing.

As described in the extension request, X17 and Y9 potatoes have been genetically engineered through the insertion of genetic elements from plant pest organisms listed in 7 CFR 340.2. APHIS previously completed a plant pest risk assessment (PPRA) associated with the insertion of these same genetic elements into potatoes during the review of the antecedent variety, Innate™ Russet Burbank event W8 potato, and concluded that the resulting organisms did not pose a plant pest risk.

X17 and Y9 potatoes express the same resistance for late blight resistance, low acrylamide potential, reduced black spot bruising, and lowered reducing sugars as the antecedent potato. APHIS prepared a plant pest risk similarity assessment (PPRSA) to compare X17 and Y9 potatoes to the antecedent. As described in the PPRSA, X17 and Y9 potatoes were obtained by introducing the same construct used to produce Innate™ Russet Burbank event W8 into the Ranger Russet variety (X17) and Atlantic variety (Y9). Based on our PPRA for the antecedent and the similarity between X17 and Y9 potatoes and the antecedent based on the PPRSA, APHIS has concluded that X17 and Y9 potatoes are unlikely to pose a plant pest risk.

The environmental assessment (EA) for the antecedent organism was prepared using data submitted by Simplot, a review of other scientific data, and field tests conducted under APHIS oversight. The EA was prepared to provide the APHIS decisionmaker with a review and analysis of any potential environmental impacts associated with the proposed determination of nonregulated status of the antecedent potato. The EA was prepared in accordance with (1) the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 et seq.); (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508); (3) USDA regulations implementing NEPA (7 CFR part 1b); and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Based on the similarity of X17 and Y9 potatoes to the antecedent potato, APHIS has prepared a preliminary finding of no significant impact (FONSI) on X17 and Y9 potatoes using the EA prepared for W8 potato. APHIS considered the following alternatives: (1) Take no action, i.e., APHIS would not change the regulatory status of X17 or Y9 potatoes and it would continue to be a regulated article, or (2) make a determination of nonregulated status of X17 and

Y9 potatoes. APHIS' preferred alternative is to make a determination of nonregulated status of X17 and Y9 potatoes.

APHIS has carefully examined the existing NEPA documentation completed for W8 potato and has concluded that Simplot's request to extend a determination of nonregulated status to X17 and Y9 potatoes encompasses the same scope of environmental analysis as the antecedent potato.

Based on APHIS' analysis of information submitted by Simplot, references provided in the extension request, peer-reviewed publications, information analyzed in the EA, and the similarity of X17 and Y9 potatoes to the antecedent organisms, APHIS has determined that X17 and Y9 potatoes are unlikely to pose a plant pest risk. We have, therefore, reached a preliminary decision to approve the request to extend the determination of nonregulated status of W8 potato to X17 and Y9 potatoes, whereby X17 and Y9 potatoes would no longer be subject to our regulations governing the introduction of certain genetically engineered organisms.

Paragraph (e) of § 340.6 provides that APHIS will publish a notice in the Federal Register announcing all preliminary decisions to extend determinations of nonregulated status for 30 days before the decisions become final and effective. In accordance with § 340.6(e) of the regulations, we are publishing this notice to inform the public of our preliminary decision to extend the determination of nonregulated status of the antecedent potato to X17 and Y9 potatoes.

APHIS will accept written comments on its preliminary determination and the preliminary FONSI regarding a determination of nonregulated status of X17 and Y9 potatoes for a period of 30 days from the date this notice is published in the Federal Register. The preliminary FONSI, as well as the extension request, supporting documents, and our preliminary determination for X17 and Y9 potatoes, are available for public review as indicated under

ADDRESSES and FOR FURTHER INFORMATION CONTACT above. Copies of these documents may also be obtained by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

After the comment period closes, APHIS will review all written comments received during the comment period and any other relevant information. All comments will be available for public review. After reviewing and evaluating the comments, if APHIS determines that no new information has been received that would warrant APHIS altering its preliminary regulatory determination or FONSI, our preliminary regulatory determination will become final and effective upon notification of the public through an announcement on our Web site at http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml.

APHIS will also furnish a response to the petitioner regarding our final regulatory determination. No further Federal Register notice will be published announcing the final regulatory determination regarding X17 and Y9 potatoes.

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 19th day of September 2016.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.
[FR Doc. 2016-22928 Filed: 9/22/2016 8:45 am; Publication Date: 9/23/2016]